MEDICA DEPOT

JUVÉDERM® VOLIFT® RETOUCH with Lidocaine Product Specifications

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EN Only for professional use

FR Réservé à un usage professionnel

DE Ausschließlich für die Anwendung durch Ärzte vorgesehen

ES Solo para uso profesional

IT Riservato per uso professionale

PT Apenas para uso profissional

TR Sadece profesyonel kullanım içindir

NO Kun til profesjonell bruk

SV Endast för professionell användning

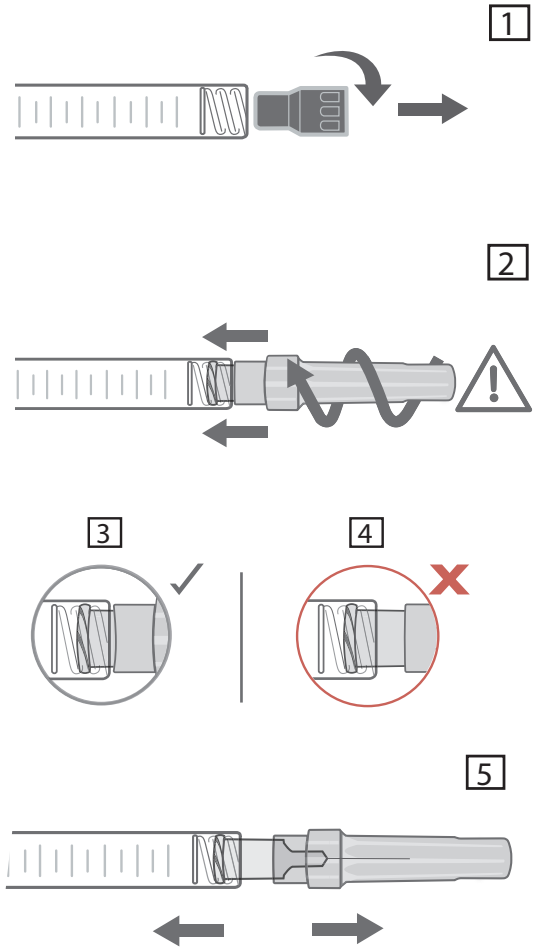
DA Kun beregnet til professionel brug

NL Alleen voor professioneel gebruik

PL Wyłącznie do użytku profesjonalnego

UK Лише для професійного використання

RU Только для профессионального использования



EN

COMPOSITION

Hyaluronic Acid gel	17.5 mg
Lidocaine hydrochloride	3 mg
Phosphate buffer pH 7.2 q.s.	1 mL

One syringe contains 0.55mL of ***Juvéderm® VOLIFT® Retouch***.

DESCRIPTION

Juvéderm® VOLIFT® Retouch is a sterile pyrogen-free physiological solution of cross-linked hyaluronic acid which is not of animal origin. The gel is presented in a graduated, pre-filled, disposable syringe. Each box contains two 0.55 mL ***Juvéderm® VOLIFT® Retouch*** syringes, 4 single-use 30G1/2" sterile needles to be used only for injecting ***Juvéderm® VOLIFT® Retouch***, an instruction leaflet and a set of labels in order to ensure traceability.

STERILISATION

The contents of the ***Juvéderm® VOLIFT® Retouch*** syringes is sterilised by moist heat.
The 30G1/2" needles are sterilised by radiation.

INDICATIONS

• ***Juvéderm® VOLIFT® Retouch*** is an injectable implant intended for the treatment of any deep skin depressions due to conditions such as premature aging.
• ***Juvéderm® VOLIFT® Retouch*** can also be used for face contouring and volume restoration to correct facial structural defects such as asymmetry, contour deformities, volume loss in the lips, cheeks, chin, lower face…
• ***Juvéderm® VOLIFT® Retouch*** is intended to be used via deep dermis or lips mucosa injection by an authorized medical practitioner.
• The presence of lidocaine is meant to reduce the patient's pain during treatment.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm® VOLIFT® Retouch*** in the periorbital area (eyelids, under-eye area, crow's feet) and glabellar region.
• Do not inject into the blood vessels (intravascular). Intravascular injection may lead to embolization, occlusion of the vessels, ischemia or infarction.
• Do not overcorrect.
• ***Juvéderm® VOLIFT® Retouch*** must not be used in:
- Patients suffering from untreated epilepsy ;
- Patients who tend to develop hypertrophic scarring ;
- Patients with known hypersensitivity to hyaluronic acid and/or to gram positive bacterial proteins as hyaluronic acid is produced by *Streptococcus* type bacteria ;
- Patients with known hypersensitivity to lidocaine or to amide-type local anaesthetics ;
- Patients suffering from porphyria ;
- Women who are pregnant or breastfeeding ;
- Children.
• ***Juvéderm® VOLIFT® Retouch*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes, etc.).
• ***Juvéderm® VOLIFT® Retouch*** should not be used simultaneously with laser treatment, deep chemical peels or dermabrasion. For surface peels, it is recommended not to inject the product if the inflammatory reaction generated is significant.

PRECAUTIONS FOR USE

• ***Juvéderm® VOLIFT® Retouch*** is indicated only for intra-dermal injections and injections in the mucous membrane of the lips.
• Medical practitioners must take into account the fact that this product contains lidocaine.
• ***Juvéderm® VOLIFT® Retouch*** is not intended for use in breast augmentation/reconstruction.
• As a matter of general principle, injection of a medical device is associated with a risk of infection. Standard precautions associated with injectable materials shall be followed.
• There is no available clinical data about injection of ***Juvéderm® VOLIFT® Retouch*** into an area which has already been treated with a non–ALLERGAN dermal filler.
• It is recommended not to inject into a site which has been treated with a permanent implant.
• No clinical data is available regarding the efficiency and tolerance of ***Juvéderm® VOLIFT® Retouch*** injections in patients having a history of, or currently suffering from, autoimmune disease or autoimmune deficiency or being under immunosuppressive therapy. The medical practitioner shall therefore decide on the indication on a case-by-case basis, according to the nature of the disease and its corresponding treatment, and shall also ensure the specific monitoring of these patients. In particular, it is recommended that these patients undergo a preliminary skin testing for hypersensitivity, and to refrain from injecting the product if the disease is active.
• There is no available clinical data concerning the tolerance of ***Juvéderm® VOLIFT® Retouch*** injection in patients presenting a history of severe and/or multiple allergies. The medical practitioner shall therefore decide on the indication on a case-by-case basis, according to the nature of the allergy, and shall also ensure the specific monitoring of these at-risk patients. In particular, the decision may be taken to propose a skin testing for hypersensitivity or suitable preventive treatment prior to any injection. In case of history of anaphylactic shock, it is recommended not to inject the product.
• Patients showing a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be subjected to a skin testing for hypersensitivity before any injection is administered. In the event of acute rheumatic fever with heart complications, it is recommended not to inject the product.
• Patients on anti-coagulation medication or using substances that can prolong bleeding (warfarin, acetylsalicylic acid, nonsteroidal anti-inflammatory drugs, or other substances known to increase coagulation time such as herbal supplements with garlic or ginkgo biloba, etc.) must be warned of the potential increased risks of bleeding and haematomas during injection.
• There is no data available regarding the safety of injecting greater amount than 20 mL of ALLERGAN dermal fillers per 60 kg (130 lbs) body mass per year.
• Due to presence of lidocaine, the combination of ***Juvéderm® VOLIFT® Retouch*** with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is not recommended.
• Due to presence of lidocaine, ***Juvéderm® VOLIFT® Retouch*** should be used with caution in patients showing symptoms of cardiac conduction disorders.
• Please recommend that the patient not use any makeup during the 12 hours following the injection treatment and that any extended exposure to the sun, UV rays and temperatures below 0°C be avoided, as well as any sauna or hammam sessions during the two weeks following the injection treatment.
• The composition of this product is compatible with fields used for magnetic resonance imaging.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. ***Juvéderm® VOLIFT® Retouch*** should therefore never be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.
There is no known interaction with other local anaesthetics.

UNDESIRABLE EFFECTS

The patients must be informed that there are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. These include, but are not limited to:
• Inflammatory reactions (redness, oedema, erythema, etc.) which may be associated with itching and/or pain on pressure and/or paresthesia, occurring after the injection. These reactions may last for a week. In particular, it has to be noticed that injection in the mucous membrane may cause more oedema and bruising due to the specific physiology of theses tissues. Besides, a preventive anti-inflammatory treatment by a medical practitioner can be recommended.

• Haematomas.
• Induration or nodules at the injection site.
• Staining or discolouration of the injection site might be observed, especially when HA dermal filler is injected too superficially and/or in thin skin (Tyndall effect).
• Poor effect or weak filling effect.
• Rare but serious adverse events associated with intravascular injection of dermal fillers in the face and tissue compression have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis and damage to underlying structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in the vision, signs of stroke, blanching of the skin or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate medical practitioner specialist should an intravascular injection occur. Abscesses, granuloma and immediate or delayed hypersensitivity after hyaluronic acid and/or lidocaine injections have also been reported. It is therefore advisable to take these potential risks into account.
• Patients must report inflammatory reactions which persist for more than one week, or any other side effect which develops, to their medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.
• Any other undesirable side effects associated with injection of ***Juvéderm® VOLIFT® Retouch*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE - POSOLOGY
• This product is designed to be injected into the dermis or the mucous membrane of the lips by an authorized medical practitioner in accordance with local applicable regulation. In order to minimize the risks of potential complications and as precision is essential to a successful treatment, the product should be only used by medical practitioners who have appropriate training and experience in injection techniques for filling skin depression, face contouring and volume restoration. They have to be knowledgeable about the anatomy at and around the site of injection.
• Use of the supplied 30G1/2" needle is recommended. However, depending on the medical practitioner's preferred injection technique, it is possible to use a 25G, 27G or 30G sterile cannula (please refer to the list hereunder). Choice of cannula length is determined by the user according to his/her injection technique. For lip indication, the use of 25G cannula (please refer to the list below) is not recommended.

Material Number	Description
94323/HPC30019ACSH	Easyflow System-20* cannula 30G x 19mm.
94324/HPC30025ACSH	Easyflow System-20* cannula 30G x 25mm.
94325/HPC27025ACSH	Easyflow System-20* cannula 27G x 25mm.
94326/HPC27038ACSH	Easyflow System-20* cannula 27G x 38mm.
94327/HPC25038ACSH	Easyflow System-20* cannula 25G x 38mm.

• Contra-Indications, Method of use, Precautions for use and Warnings defined for the needle in this leaflet apply also to the cannula referenced above if used with this product.
• ***Juvéderm® VOLIFT® Retouch*** is to be used as supplied. Modification or use of the product outside the Directions for Use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured.
• Prior to treatment, medical practitioners shall inform their patients about the product's indications, contra-indications, incompatibilities and potential undesirable effects/risks associated with dermal fillers injection and ensure that patients are aware of signs and symptoms of potential complications.
• The area to be treated should be disinfected thoroughly prior to the injection.
• Remove tip cap by pulling it straight off the syringe as shown in fig. 1. Then firmly push the needle provided in the box (fig. 2) into the syringe, screwing it gently clockwise. Twist once more until it is fully locked and has the needle cap in the position shown in fig. 3. If the needle cap is positioned as shown in fig. 4, it is incorrectly attached.
Next, remove the protective cap by holding the body of the syringe in one hand, the protective cap in the other, as shown in fig. 5, and pulling the two hands in opposite directions.
Prior to injecting, depress the plunger rod until the product flows out of the needle.
Inject slowly and apply the least amount of pressure necessary.
If the needle is blocked, do not increase the pressure on the plunger rod. Instead, stop the injection and replace the needle.
Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level and/or increase the risk of vascular compromise.
• After needle insertion and before injection, it is recommended to withdraw slightly the plunger to aspirate and verify the needle is not intravascular.
• If immediate blanching occurs at any time during the injection, the injection should be stopped and appropriate action taken such as massaging the area until its return to a normal color.
• The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue and the injection technique. The amount injected will depend on the areas which are to be corrected based on the experience of the medical practitioner.
• Do not overcorrect as injection of an excessive volume can be at the origin of some side effects such as tissue necrosis and oedema.
• ***Juvéderm® VOLIFT® Retouch*** can also be used to achieve and maintain optimal correction after an initial treatment with ***Juvéderm® VOLIFT® with Lidocaine*** or with any other Allergan dermal filler intended for the treatment of deep cutaneous depressions, for facial contouring or for restoration of volume (refer to section "Indications" of the relevant DFU).
• It is recommended to wait until any side effects are resolved (with a minimal interval of 2 weeks) between two injections.
• It is important to massage the area treated after the injection in order to ensure that the substance has been uniformly distributed.

WARNINGS
• Check the expiry date on the product label.
• In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe.
• Do not re-use. Sterility of this device cannot be guaranteed if the device is re-used.
• Do not re-sterilise.
• For the needles (CE 0123 TSK Laboratory, Japan):
- Used needles must be thrown away in the appropriate containers. Do the same for the syringes. Please consult the current applicable directives to ensure their correct elimination.
- Never try to straighten a bent needle; throw it away and replace it.

STORAGE CONDITIONS
• Store between 2°C and 25°C.
• Fragile.

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